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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/392,024	09/08/1999	BRUCE L. RISER	FG0810	9469

7590 07/17/2003

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EXAMINER

NOLAN, PATRICK J

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 07/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/392,024</b>	Applicant(s) <b>Riser et al.</b>
Examiner <b>Patrick J. Nolan</b>	Art Unit <b>1644</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on May 7, 2003

2a)  This action is **FINAL**.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 14-16 and 19-35 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 14, 15, 19, 20, 22-24, 26, 27, 29, 30, 32, 33, and 35 is/are rejected.

7)  Claim(s) 16, 21, 25, 28, 31, and 34 is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other: \_\_\_\_\_

**Part III DETAILED ACTION**

1. This application is a continuation-in-part of 60/099,471 and 60/112,855.
2. Claims 14-16 and 19-35 are pending.
3. The following new ground of rejection is necessitated by Applicant's amendment submitted 5-07-03

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103<sup>®</sup> and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 14, 15, 19-20, 22-24, 26-27, 29-30, 32-33 and 35 are rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,232,064 in view of U.S. Patent 5,545,533 and Ito et al. (JASN Vol. 9, page 538A, Sept 1997, reference 26 on the IDS submitted 9-10-01).

The '064 patent teaches diagnosing kidney fibrosis in patients by detecting CTGF in a sample with an antibody and comparing it with a standard (claims 1-2 and column 5, in particular).

The '064 patent doesn't teach the actual specific diseases

recited in claims known to be caused in part by fibrosis of the kidney.

Ito et al., teaches CTGF mRNA detected by Northern analysis is significantly upregulated in Kidney biopsy material taken from patients with diabetic nephropathy, focal glomerulosclerosis and glomerulonephritis. The '533 patent teaches that Northern analysis is an indirect mechanism to detect the amount of the expressed protein and that western analysis by the use of antibodies is best for diagnostics (columns 1-2).

Therefore one of skill in the art at the time the invention was made would have been motivated to substitute mRNA as taught by Ito et al., with antibody to CTGF protein, as taught by the '064 patent to diagnose glomerulonephritis, glomerulosclerosis or diabetic nephropathy because detection of proteins by Western analysis is the most direct mechanism to measure to assess protein levels for diagnostics, as taught by the '533 patent. It is noted claims 27, 29, 30, 32, 33 and 35 are included because diabetes, hypertension and hyperglycemia are all directly involved in the diseases of diabetic nephropathy.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

6. Applicant is notified that claims 16, 21, 25, 28, 31 and 34 are free of the art.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this

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application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

*Patrick J. Nolan*  
Patrick J. Nolan, Ph.D.  
Primary Examiner, Group 1640  
July 16, 2003